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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,661

02/01/2006

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EXAMINER

PITRAK, JENNIFER S

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,661	Applicant(s) AOKI, MIKIO	
	Examiner JENNIFER PITRAK	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 9-48 and 50-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/05/2005; 03/06/2006; 07/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-21 and 49 in the reply filed on 12/20/2007 is acknowledged. The traversal is on the ground(s) that the Gopal reference applied to demonstrate that the special technical feature does not make a contribution over the prior art is not applicable to the instant invention because Gopal, et al. do not teach a hypertonic solution and that the instant invention is characterized by the use of osmotic pressure shock. This is not found persuasive because regardless of whether Gopal, *et al.*, teach the special technical feature, the claims do not make a contribution over the prior art as evidenced by the art rejections cited in this Office Action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22-48 and 50-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/20/2008.

Applicant's election without traverse of the following species in the reply filed on 12/20/2007 is acknowledged: (1) for the oligonucleotide, a double-stranded oligonucleotide; (2) for the specific backbone and/or sugar modification, an siRNA; (3) for the hypertonic solution substance, oligosaccharide; (4) for the oligosaccharide, sucrose. The species election among the types of oligonucleotides and specific backbone and/or sugar modifications [(1) and (2) above] is **withdrawn** in light of the fact that the distinction among these species is relevant only to the

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biological activity of these different species, but the distinction is not relevant to a method of nucleic acid infusion to which the instantly elected invention is directed.

Claims 9-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species as indicated by the Applicant, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/20/2007.

Claims 1-8 and 49 are under examination.

Claim Objections

Claim 49 is objected to because of the following informalities: the claim recites “wherein the hypotonic solution has isotonic osmotic pressure or lower.” It is not clear how a hypotonic solution can also be isotonic.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 49 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morcos, *et al.* (2004, U.S. Patent 6,228,392, first citation on 07/20/2006 IDS).

The claims are to a method of nucleic acid infusion comprising (a) bringing a nucleic acid, a hypertonic solution, and cells into contact with each other and (b) lowering osmotic pressure of the hypertonic solution after step (a), wherein step (b) comprises bringing a

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hypotonic solution and the cells into mutual contact, wherein the hypertonic solution comprises sucrose and wherein the hypotonic solution has isotonic osmotic pressure or lower.

Morcos, *et al*, teach a method of nucleic acid infusion comprising contacting cells first with a hypertonic solution followed by addition of an isotonic solution (see columns 1 and 2). The inventors teach the method is useful for delivering antisense oligonucleotides, morpholino oligonucleotides, DNAs, and other biological hydrophilic substances to cells (column 1). The inventors specifically teach the infusion method comprising two steps: (a) contacting the cells with a hypotonic composition containing the molecule (nucleic acid, for example) to be delivered to the cells and (b) adding isotonic cell culture medium (see bottom of column 2 to top of column 3). In Figure 4, sucrose is shown to have a high relative cytosolic delivery as the hypertonic solution component compared to other sugars used for infusion. Thus, Morcos, *et al*. clearly anticipate the instant claims 1-8 and 49.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak, PhD
Examiner
Art Unit 1635

/Tracy Vivlemore/
Examiner, Art Unit 1635